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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER 20747/270

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
PRIORITY DATE CLAIMED CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PCT/GB2003/004117 17 September 2003 (17.09.2003) 17 September 2002 (17.09.2002) TITLE OF INVENTION See 1 in Addendum APPLICANT(S) FOR DO/EO/US THOMSON, Axel Andreas Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. X The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. X Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). Other items or information: See Attachment 2

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Page 1 of 2

DT15 Rec'd PCT/PTO 1 7 MAR 2005

PTO-1390 (Rev. 02-2005)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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U.S. APPLICATION	NO. (if known	, see 37 CFR 1.			ATTORNEY'S DOC	KET NUMBER	
1	0/52	8207	PCT/GB200	03/004117	20747/2	270	
The following fees have been submitted					CALCULATIONS	PTO USE ONLY	
21. X Basic national fee\$300					\$ 300.00		
22. X Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)					\$ 200.00		
23. X Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority					400.00 \$		
TOTAL OF 21, 22 and 23 =					\$ 900.00		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.							
Total Sheets E	xtra Sheets		ch additional 50 or fraction up to a whole number)	RATE			
77 - 100 =	-23 _{/50} =			x \$250	\$ 0.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).					\$ 130.00		
CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$.		
Total claims		17 - 20 =	0	× \$50	\$ 0.00		
Independent claims		5 -3=	2	x \$200	\$ 400.00		
MULTIPLE DEPENDENT CLAIM(S) (if applicable				+ \$360	\$ 0.00	1	
TOTAL OF ABOVE CALCULATIONS =					\$ 1,430.00		
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					0.00	1	
SUBTOTAL =					\$ 1,430.00	•	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).					\$ 0.00		
TOTAL NATIONAL FEE =					\$ 1,430.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +					\$ 0.00		
TOTAL FEES ENCLOSED =					\$	1,430.00	
					Amount to be	\$	
					refunded: Amount to be	\$	
a X A check in the amount of \$ 1.430.00 to cover the above fees is enclosed					charged:	L *	
To solve the distribution of the solve to solve the distribution.							
b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.							
c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1138. A duplicate copy of this sheet is enclosed.							
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.							
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.							
SEND ALL CORRESPONDENCE TO:							
Edwin V. Merkel SIGNATURE							
Nixon Peabody LLP					-ul-a1		
Clinton Square Edwin V. Me					егкеі		
P. O. Box 31051	Rochester, NY 14603-1051 40,087						
United States of America REGISTRATION NUMBER							

Addendum

1. A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Attachment 2

UNSIGNED Combined Declaration and Power of Attorney. Verified Statement Re Sequence Listing.

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Preliminary Amendment

(6 pages) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett

(Typed or printed name of person mailing paper or fee)

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Unsigned Combined Declaration and Power of Attorney (2 pages) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett
or printed name of per

(Typed or printed name of person mailing paper or fee)

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Sequence Listing on Diskette and Verified Statement re Sequence Listing of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett

(Typed or printed name of person mailing paper or fee)

DT15 Rec'd PCT/PTO 1 7 MAR 2005

EXPRESS MAIL CERTIFICATE

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE TITLE:

> EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Transmittal Letter to the U.S. Designated/Elected Office (DO/EO/US) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

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Shawn Lockett

(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or

fee)

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Information Disclosure Statement with PTO-1449 forms (3 pages) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett

(Typed or printed name of person mailing paper or fee)